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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,714	01/22/2004	Maxwell Gordon	1360-001	5204

47888 7590 02/02/2010

HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
02/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/762,714
Filing Date: January 22, 2004
Appellant(s): GORDON, MAXWELL

James Costigan
Registration No. 25,669
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 13, 2009 appealing from the Office action mailed March 31, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of the Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

7,144,587 Oshlack 12-2006

Meissner et al. "Oral naloxone reverses opioid-associated constipation" Pain 84, (2000), 105-109.

(9) Grounds of Rejection

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 16-18 and 21-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US Patent 7,144,587) in view of Meissner et al (Pain 84, 2000, 105-109).

Oshlack et al. teach solid dosage forms of compositions comprised of an opiate, an opiate antagonist and a hydrocolloid containing excipient (meeting the limitation of claim 1; Col. 6, lines 16-20). More specifically the opiates are chosen from agents such as morphine, codeine and oxycodone (meeting the limitation of claims 2-3; see Col. 12, lines 34-56 for a more complete list). Antagonists that are useful in the invention include naltrexone and naloxone (meeting the limitation of claims 4-5; lines 14-15). Dosage forms are taught that include coated beads including the composition (meeting the limitation of claim 6; Col. 17, lines 23-61). In regards to the limitation that the amount of the enteric coated opiate antagonist pellets is effective to prevent opiate induced constipation, it would be obvious that because Oshlack et al. teach coated

beads, it would necessarily prevent opiate induced constipation. It is taught that gelling agents or other excipients are included in the dosage forms, which include starch and starch derivatives, lactose, xanthan gum, locust bean gum, microcrystalline cellulose, alginates, dicalcium phosphate (dibasic calcium phosphate) and magnesium stearate (Col. 7, lines 20-47; Col. 16, lines 48-55 and Example 6). It is noted that the teaching of dicalcium phosphate renders the monocalcium phosphate obvious because the compounds are similar and have similar properties of being excipients. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the Applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). The gelling agents impart a gel-like quality to the dosage form if it is tampered with and prevent abuse of the dosage form by minimizing absorption (Col. 7, lines 48-55). It is further taught that when the dosage form is tampered with and exposed to a small amount of a liquid such as water, the dosage form will be unsuitable for injection (meeting the limitation of claim 18; Col. 3, lines 12-16). Table 1 exemplifies a composition comprised of oxycodone with naloxone. Further, Oshlack et al. teaches that the opiate/opioid antagonist formulation together with a hydrocolloid can be formulated in immediate release formulations or controlled release in any suitable tablet (Col. 17, lines 12-15), and teaches coated beads that can contain the opiate, the opiate antagonist and hydrocolloid. Therefore, it would be obvious that one tablet could contain beads that are controlled and immediate release (meeting the limitation of claim 16-17). Further, because Oshlack et al. teach compositions comprised of the same components, it

would be obvious that the composition would be released in the same areas, such as the colon (further addressing claim 16).

Oshlack et al. does not specifically teach a compound comprised of all the ingredients listed in claim 1 nor does it teach that the composition is used in a method of treating constipation.

Meissner et al. teaches improved laxation during oral naloxone treatment in opioid-associated constipation (see whole document).

Accordingly, it would be obvious to a person having ordinary skill in the art at the time of the invention to formulate a composition comprised of an opiate, an opiate antagonist, hydrocolloids and other excipients as exemplified in claim 1 because Oshlack et al. teach the suitability of all of the hydrocolloids and excipients in a composition of coated beads with an opiate and an opiate antagonist. One would be motivated to include the hydrocolloids and excipients in the composition in an effort to form a composition that when tampered with will impart a gel-like quality to avoid abuse of the opiate composition (as taught by Oshlack et al., Col. 7, lines 48-55). One would be further motivated to use the composition in a method of treating constipation associated with the use of opioids because of Meissner's teachings that the combination of an opioid agonist and antagonist effectively treats constipation induced by the opiate.

(10) Response to Arguments

Appellants argue that Oshlack mentions many formulations but none having the components of claim 1; therefore, the reference would not be obvious. Appellants

further argue that Oshlack teaches the use of sequestered aversive agents that impart a gelling effect when the dosage form is not used for its intended use and that an opiate antagonist that is sequestered or non-available can have no role in reducing or preventing constipation according to the composition in claim 6 and method claim 22 which recite enteric coated antagonist pellets to reduce constipating effects.

In response to the above arguments, it is noted that Oshlack et al. does not exemplify a composition with all of the components listed in claim 1; however, Oshlack et al. teaches all of the ingredients as being useful in the composition, especially for gelling purposes in case the product is tampered with (see Col. 7, lines 20-55, Col. 16, lines 48-55 and Example 6). Oshlack does not have to exemplify an exact composition as recited in Claim 1 to render the invention obvious. Regarding Appellant's arguments that the opiate antagonist is in a sequestered form and would have no role in reducing constipation, it is noted that Oshlack teaches that the antagonist can be in a sequestered form as well as a non-sequestered form (see Col. 4, lines 35-45). Therefore, an antagonist such as naloxone will be available to reduce constipation (in which Meissner teaches that naloxone reduces constipation as discussed in the rejection).

Furthermore, the claims are drawn to a composition and the effect of reducing constipation is considered an intended use. It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the

intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

Conferees:

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616

/Renee Claytor/

Art Unit 1627